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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/553,094	04/18/2000	Scott E. Anderson	38-21(15503)B	4263

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EXAMINER
MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
1631	11

DATE MAILED: 10/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/553,094	Applicant(s) ANDERSON ET AL.	
	Examiner Marjorie A. Moran	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. All objections and rejections not reiterated below are hereby withdrawn.

Election/Restrictions

In response to the continuing traversal for restriction to a single nucleic acid sequence, applicant is directed to MPEP 803.04, which states with regard to sequence election that, "In some exceptional cases, the complex nature of the claimed material...may necessitate that the reasonable number of sequences to be selected be less than ten. In other cases, applicants may petition pursuant to 37 CFR 1.181 for examination of additional nucleotide sequences by providing evidence that the different nucleotide sequences do not cover independent and distinct inventions."

As previously set forth in the restriction requirement, due to the increasing numbers of applications reciting sequences and the increasingly large size of the sequence databases, and the fact that nonpatent databases, foreign patent databases, and US patent databases must be searched for any single sequence, the instant claims, directed to nucleic acid sequences, are considered to be so complex that a reasonable number to be searched and examined is one sequence. It is noted that applicant has not argued not provided evidence that any additional sequences are not independent and distinct from that elected. For the above reasons, the examiner maintains that the restriction requirement is proper.

Claims 1 and 8 are pending.

Claim Rejections - 35 USC § 101

Claim 1 is again rejected and new claim 8 is rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

Applicant's arguments filed 5/15/02 have been fully considered but they are not persuasive. Applicant argues that the claimed nucleic acids are useful to identify sequence motifs, for comparative sequence analysis, to transform plants, determine association with polymorphic sites, detect mutations and to detect changes in protein expression, among others. Applicant further cites 20 USPQ2d 1094, 1100 (Fed. Cir. 1991) as support for the argument that the examiner's position that "the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose" is wrong as a matter of law. In response, it is noted the specification teaches only general uses (purposes), but does not teach any specific "purpose" for the elected sequence. The uses argued above are ones which are applicable to the general class of nucleic acids and are not specific to the SEQ ID NO: elected. Applicant is directed to the previous office action for specific reasons for a lack of specific, substantial and credible utility with regard to these asserted uses as applied to elected SEQ ID NO: 1. Further, and especially with regard to identification of sequence motifs, detection of mutations, and association with polymorphic sites, applicant is reminded that a "use" to do further research (i.e. to establish a correlation between a disease and a gene, or to determine expression patterns in particular tissues) is not a specific, substantial and credible utility under 35 USC 101. For these reasons and those previously set forth in the office action of 2/15/02, the general utilities taught by the specification and argued by applicant do not constitute a specific, substantial, and credible utility for the claimed SEQ ID NO's.

Applicants also argue that practical utility of an invention may be derived from belonging to a broad class of inventions. The requirement in any particular case, however, is that practical utility can be inferred if each and every member of the broad class possesses a common utility. However, the fact situation in the instant application is not analogous to applicants' microscope or golf club examples Applicant cites several court cases in the argument regarding credibility. With regard to In re Ziegler (20 USPQ2d 1600, 1603), it is noted that the court decided that "Ziegler did not disclose any practical use for the polypropylene or its film". Again, this fact pattern is different from that of the instant application. With regard to In re Brana (34 USPQ2d 1436, 1441), the utility of Brana's compounds was based on the activity of the claimed compounds against lymphocytic leukemia, as compared to known compounds with similar activity. Applicant should note that Brana's compounds had established activity (as shown in examples) against a known disease. Similarly, in Cross vs. Iizuka (224 USPQ 739, 742), the compounds claimed were shown to have enzyme inhibitory activity related to a known therapeutic use. The instant specification does not disclose any correlation between the elected nucleic acid sequence and a known disease or disorder, therefore SEQ ID NO: 1 can not be said to have utility for the same reasons given in the Brana or Cross vs. Iizuka cases. While the examiner must treat as true any statement of fact made by an applicant unless countervailing evidence can be provided, as argued by applicant, no statements regarding a "practical" utility, other than those already addressed above, have been made by applicant with regard to the elected nucleic acid sequence. With regard to in re Gaubert and the argument that the examiner must set forth factual reasons which would lead one skilled in the art to question the asserted utilities, several facts were set forth in the previous office action. They are summarized as follows:

SEQ ID NO: 1 is not known in the prior art or disclosed to be or to comprise a sequence motif, a conserved sequence, or a polymorphic site;

No correlation has been set forth between SEQ ID NO: 1 and any phenotypic trait such that SEQ ID NO: 1 may be used to identify, follow, detect, etc. change sin protein expression, a mutation, changes in growth characteristics, etc.;

SEQ ID NO: 1 is known in the prior art and has not been disclosed to encode any protein or peptide.

Given the facts previously set forth and reiterated above, one skilled in the art would reasonably doubt that the elected sequence can be used for the utilities asserted and argued by applicant. With regard to credibility arguments, the examiner did NOT state that credibility was not assessed, as argued by applicant. There is no such statement on page 7 of the office action, as argued by applicant. In fact, there are at least three statements on page 7 which state that SEQ ID NO: 1 does not have a "specific, substantial, and credible utility". Further, for every asserted utility addressed in the office action of 2/15/02, the examiner discussed whether the utility was specific, substantial and credible for elected SEQ ID NO: 1.

For the reasons set forth above and previously set forth, the examiner maintains that the claims lack utility, therefore the rejection of claim 1 is maintained and claim 8 is rejected.

Claims 1 and 8 are also rejected under 35 U.S.C. 112, first paragraph for not being enabled.

Applicant's arguments filed 5/15/02 have been fully considered but they are not persuasive. Applicant argues that as the claimed nucleic acid sequences have utility, they are enabled. This enablement rejection is linked to the utility rejection, as previously set forth. As

the utility rejection is maintained, the enablement rejection of claim 1 is also maintained and claim 8 is rejected.

Claim Rejections - 35 USC § 112, 1rst paragraph

Claim 1 is again rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a LACK OF WRITTEN DESCRIPTION rejection.

Applicant's arguments filed 5/15/02 have been fully considered but they are not persuasive. In response to the argument that the assertion that the specification "fails to teach that SEQ ID NO: 1 encodes any polypeptide, specifically a maize protein" is unfounded, it is noted that the specification, as previously set forth, does not teach any polypeptide sequences, does not discloses any ORF's, and does not otherwise disclose any information with regard to any polypeptide sequence putatively or possibly encoded by SEQ ID NO: 1. Applicant does not point to any support in the originally filed specification or provide any other evidence to show that the examiner's statement is unfounded; i.e. there is no support or evidence that SEQ ID NO: 1 does indeed encoded a protein or peptide.

Applicant argued that the specification discloses SEQ ID NO: 1; this is not in question. However, the claims also embody full length cDNA and/or genomic sequences which are not described by the specification. SEQ I DNO: 1, as previously set forth, comprises several ATG (start) codons. It is not known whether any of these is the "start" of a full ORF comprised within SEQ IDNO: 1 itself, or is the "start" of a larger ORF wherein SEQ ID NO: 1 encodes only

a portion of a protein which is actually encoded by an ORF in the larger sequence embodied by the open claim language of claim 1. Therefore, although a sequence consisting of SEQ ID NO: 1 is fully described, it is unknown whether SEQ ID NO: 1, itself, is a sequence which encodes a maize protein, as claimed. As the specification does NOT describe any protein or peptide encoded by SEQ ID NO: 1, then there is not a full and complete description of the invention recited in claim 1. Applicant further argues that SEQ I DNO: 1 was isolated from Zea mays. In response, it is noted that while the nucleic acid sequence was isolated from corn (maize), the specification does not disclose whether a protein or peptide encoded by SEQ ID NO: 1 is specific to corn, or may be one which is found in a variety of organisms.

Applicant's arguments with respect to splice variants, mutations, etc., and with respect to cDNA are moot as the rejection is not directed to a lack of description of any of these, but is directed to a lack of description of a nucleic acid molecule encoding a maize protein, wherein the nucleic acid molecule is SEQ ID NO: 1.

As the specification does not disclose any protein or peptide encoded by SEQ ID NO: 1, particularly one which is known to be specific to maize, the rejection of claim 1 is maintained.

Conclusion

Claims 1 and 8 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to a patent analyst, Tina Plunkett, whose telephone number is (703) 305-3524.

Marjorie A. Moran
Examiner
Art Unit 1631

October 21, 2002

JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER